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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,244	11/29/2000	Gervais Dionne	IAF-16-RE	1171

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/726,244	DIONNE ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reissue Applications

1. Since the litigation related to this reissue application is terminated and final, action in this reissue application will NOT be stayed. Due to the related litigation status of this reissue application, EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR 1.136(a) WILL NOT BE PERMITTED.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-8, 13-15, 20-22, 27-29, 35-37, 43-45, 51-53, and 61-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims 6-8, 13-15, 20-22, 27-29, 35-37, 43-45, and 51-53 are drawn to ester compounds "wherein the 2-hydroxymethyl group is replaced by R-CO-". There is no support for this limitation in the specification as filed. The specification teaches ester compounds wherein "the hydrogen of the 2-hydroxymethyl group is

replaced by an acyl function" (does not teach replacement of the entire 2-hydroxymethyl group).

4. Claims 6, 13, 20, 27, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims 6, 13, 20, 27, and 35 are drawn to ester compounds "wherein the 2-hydroxymethyl group is replaced by R-CO- and R is...alkylsulphonyl or aralkylsulphonyl". There is no support for this limitation in the specification as filed. The specification teaches ester compounds wherein the hydrogen of the 2-hydroxymethyl group is replaced by an acyl function; sulphonate esters such as alkylsulphonyl or aralkylsulphonyl; amino acid esters, and phosphate esters.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 11, 13, 18, 20, 25, 27, 32, 35, 40, and 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 13, 20, 27, 35, and 61-64 recite the phrase "replaced by R-CO- and R is...alkylsulphonyl or aralkylsulphonyl" which renders said claims indefinite. When R is alkylsulphonyl or aralkylsulphonyl the formation of a carbonyl ester is not possible.

Claims 11, 18, 25, 32, and 40 recite the term "derived from". In the absence of a chemical name or structure, one of ordinary skill in the art would not be apprised of the metes and bounds of the instant invention since applicant has failed to particularly point out the modifications to the chemical core which would effectuate the derivatization.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

8. Claims 1-5, 9-12, 16-19, 23-26, 30-34, 38-42, 46-50, 54-60, and 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,703,396 (Liotta).

Liotta discloses the (-)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5yl)-(1H)-pyrimidin-2-one and pharmaceutically acceptable salts and esters thereof wherein the (+)-enantiomer is present in an amount less than 1% w/w (claims 1-28). Liotta further teaches mono-, di-, and triphosphate derivatives and a

number of 5'-O-acyl derivatives (column 5, line 3 to column 6, line 12; column 16, line 53 to column 54, line 21). The most effective acyl group to be used to esterify the C5'-position of the nucleoside can be determined without undue experimentation by evaluation of a number of homologs using the selected enzyme system. For example, when 1,3-oxathiolane nucleosides are esterified with butyric acid, resolutions with both pig liver and esterase and Amano PS-800 proceed with high enantioselectivity (94-100 enantiomeric excess) and opposite selectivity. Other esters include the acetate, propionate, α-haloesters. Pharmaceutically acceptable salts are known to those in the art and include those derived from pharmaceutically acceptable inorganic and organic acids and bases (column 14, line 54 to column 15, line 10). Examples of suitable inorganic acids include hydrocholoric, hydrobromic, sulfuric, nitric, maleic, formic, acetic, citric, and lactic acids. Salts derived from appropriate bases include alkali metal, alkaline earth metal, ammonium and quaternary amine. The active compound is included in the pharmaceutically acceptable carrier or diluent in an amount sufficient to deliver to a patient a therapeutically effective amount of the compound to inhibit viral replication. The compound is conveniently administered in unit dosage form: for example containing 7 to 7000 mg, preferably 70-1400 mg of active ingredient per unit dosage form. Variations and modifications of the invention, a method of resolution and antiviral activity of nucleoside enantiomers, will be obvious to those skilled in the art from the foregoing detailed description of the invention (column 17, lines 15-21).

9. Claims 1-5 are rejected under 35 U.S.C. 102(g) as being anticipated by Liotta et al. US 6,703,396 (Liotta).

The rejection of claims 1-5 above based upon count 1 of Interference No. 104,333, to which applicant is a party. Claims 1-5 must be canceled.

Conclusion

10. Claims 1-68 are pending. Claims 1-68 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

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